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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,518	03/01/2005	Norbert Heske	289-PDD-03-07 US	6401

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C. R. Bard, Inc.
Bard Peripheral Vascular, Inc.
1415 W. 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

EXAMINER	
LLOYD, EMILY M	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,518	HESKE ET AL.	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004 and 05 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-100* is/are pending in the application.

4a) Of the above claim(s) *58-65 and 69-97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57,66-68 and 98-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20040629, 20041005, 20041230, 20050217, 20051011, 20080925.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group B in the reply filed on 5 January 2009 is acknowledged. The traversal is on the ground(s) that Dejter, Jr. et al. is "intended to be held by two hands for use in a two-handed operation" (Applicant's 5 January 2009 response, paragraph bridging the first and second pages). This is not found persuasive because Applicant's limitation in claim 57 is "wherein the biopsy device can be held in a single hand of a physician" which only requires that the device be capable of being held in a single hand, and the device of Dejter, et al. is capable of being held in a single hand.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 58-65 and 69-97 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5 January 2009.

Information Disclosure Statement

3. The information disclosure statements filed 29 Jane 2004 and 11 October 2005 fail to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 depends on "the biopsy device according to claim 68", and it is unclear what this is claiming. For the purpose of examination, the Examiner has interpreted claim 68 as depending on claim 67, as similar claim 100 depends on claim 99 (which is similar to claim 67).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 4989614 (Dejter, Jr et al.).

Dejter, Jr et al. disclose a biopsy device for tissue collection (Figures 13-18), comprising: a housing (casing 1 Figure 13) containing a power source (battery 92 (not shown) in chamber 90 Figure 13); and a removable element (disposable syringe assembly Column 4 lines 8-10), comprising a biopsy needle module (needle 2 Figure 13) and a pressure source (syringe 4 and plunger 5 Figure 13), wherein the removable

element is configured for integration into the housing (Figure 13 illustrates the removable element integrated into the housing); wherein the biopsy device can be held in a single hand of a physician, having no cables or lines extending from the housing to external units (Figure 13).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 66 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dejter, Jr et al.

Regarding claims 66 and 98, Dejter, Jr et al. disclose the biopsy device of claim 57 (see 102(b) rejection of claim 57 by Dejter, Jr et al.), and further disclose that the housing comprises a lower housing segment (portion of casing 1 below cover 82 Figure 13) with lateral walls (walls of casing 1 leading up to cover 82 Figures 14 and 15), a housing lid matched to the lower housing segment (cover 82 Figures 1-15) and having a locking mechanism (latch 89 and release button 83 Figure 15 and Column 10 line 64-Column 11 line 7), and a first and second end lid (distal portion of casing 1 near connections 11, 81; and proximal portion of casing 1 between power switch breaker 111 and origin sensor 120 Figure 13), each connected to the lower housing segment (the distal and proximal ends are connected to casing 1). Further, having lateral walls of different heights is obvious as this is a change in shape that is obvious in the absence of persuasive evidence that this particular configuration is significant. See MPEP 2144.04 IV B Changes in Shape. Further, Dejter, Jr et al. are moot as to the direction of the locking mechanism. However, assuming that such a direction is not already longitudinally displaceable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have such a locking mechanism be longitudinally displaceable as this is a simple rearrangement of parts regarding the positioning/direction of the locking mechanism that would not have modified operation of

the device, and the direction of displacement of the locking device is an obvious matter of design choice. See MPEP 2144.04 VI C Rearrangement of Parts.

12. Claims 67, 68, 99 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dejter, Jr et al. as applied to claims 57, 66 and 98 above, and further in view of United States Patent 5964716 (Gregoire et al.).

Regarding claims 67, 68, 99 and 100, Dejter, Jr et al. teach the biopsy devices of claims 66 and 98. Dejter, Jr et al. do not expressly disclose that the first housing lid comprises a U-shaped opening at the top thereof, the opening sized to receive a portion of the removable element, and the second housing lid comprising a first and second U-shaped opening at the top thereof, wherein each of said openings are sized to receive a portion of the removable element. Gregoire et al. teach a first housing lid comprising a U-shaped opening at the top thereof, the opening sized to receive a portion of the removable element (front end lid/portion Figure 1 receives probe 45 Figure 5), and the second housing lid comprising a first and second U-shaped opening at the top thereof, wherein each of said openings are sized to receive a portion of the removable element (back plate 36 and probe 45 Figure 1, also tissue extractor 65, probe slot 39, and detent pin 82, Figures 6 and 7). While Gregoire et al. do not expressly teach the purpose of the slot left of slot 39 in Figure 7, it is clear that its size is at least big enough to receive detent pin 82. Further, such a duplication of U-shaped openings/slots would have been obvious to one having ordinary skill in the art at the time the invention was made as this "duplication of parts has no patentable significance unless a new and unexpected result is produced." (See MPEP 2144.04 VI B Duplication of Parts) It would have been

obvious to one having ordinary skill in the art at the time the invention was made to combine the housing lids comprising a U-shaped openings at the tops thereof as taught by Gregoire et al. in the invention of Dejter, Jr et al. to provide for easier insertion and removal of the removable element and to provide for using the rear/proximal end as an indicator and controller (Gregoire et al. the use of detent pin 82 to determine tissue receptacles).

13. Claims 57, 66-68 and 98-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al. as modified by Dejter, Jr et al.

Regarding claim 57, Gregoire et al. disclose a biopsy device for tissue collection (Figures 1-7), comprising: a housing (housing 31a Figure 1); and a removable element (probe 45 Figure 1 and Column 5 lines 30-44), comprising a biopsy needle module (elongated hollow piercing needle 51, cutter 60 and tissue extractor 65 Figure 2), wherein the removable element is configured for integration into the housing (Figure 1 and Column 5 lines 30-44).

As Gregoire et al.'s probe drive 31 contains a motor (Column 6 lines 40-42), it is clear that Gregoire et al. comprises a power source (in order to power the motor) but it is unclear where the power source is located. Further, it also appears that probe drive 31 can be held in a single hand of a physician. However, Dejter, Jr et al. explicitly teaches a housing (casing 1 Figure 13) containing a power source (battery 92 (not shown) in chamber 90 Figure 13); and a removable element (disposable syringe assembly Column 4 lines 8-10), comprising a pressure source (syringe 4 and plunger 5 Figure 13); and that the biopsy device can be held in a single hand of a physician,

having no cables or lines extending from the housing to external units (Figure 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the power source in the housing, the removable element comprising a pressure source, and the biopsy device being capable of being held in a single hand and having no cables or lines extending from the housing to external units as taught by Dejter, Jr et al with the invention of Gregoire et al. as this would provide for a single person performing the biopsy procedure (Dejter, Jr et al. Column 2 lines 45-48), and would provide for the biopsy to be performed in an outpatient setting (Dejter, Jr et al. Column 2 lines 48-53) without the need or concern for external equipment requirements (it is easier to set up and perform a biopsy when only a single apparatus is required as opposed to external vacuum sources, control units, etc.). Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make Gregoire et al. portable with the teachings of Dejter, Jr et al. as this would not provide new or unexpected results. See MPEP 2144.04 V A Making Portable.

Regarding claims 66 and 98, Gregoire et al. as modified by Dejter, Jr et al. disclose the biopsy device of claim 57 (see 103(a) rejection of claim 57 by Gregoire et al. as modified by Dejter, Jr et al.), and further disclose that the housing comprises a lower housing segment (Gregoire et al. portion of housing 31a below cover 38 Figure 1; also Dejter, Jr et al. portion of casing 1 below cover 82 Figure 13) with lateral walls (Gregoire et al. walls of housing 31a leading up to cover 38 Figure 1; also Dejter, Jr et al. walls of casing 1 leading up to cover 82 Figures 14 and 15), a housing lid matched to

the lower housing segment (Gregoire et al. cover 38 Figure 1; also Dejter, Jr et al. cover 82 Figures 1-15) and having a locking mechanism (Dejter, Jr et al. latch 89 and release button 83 Figure 15 and Column 10 line 64-Column 11 line 7), and a first and second end lid (Gregoire et al. walls of housing 31a at the distal and proximal portions of the device (where back plate 36 is the second/proximal housing lid; the portion opposite back plate 36 is the first/distal housing lid) Figure 1; also Dejter, Jr et al. distal portion of casing 1 near connections 11, 81, and proximal portion of casing 1 between power switch breaker 111 and origin sensor 120 Figure 13), each connected to the lower housing segment (Gregoire et al. housing 31a is connected to back plate 36 and the portion opposite back plate 36, Figure 1; also Dejter, Jr et al. the distal and proximal ends are connected to casing 1). Further, having lateral walls of different heights is obvious as this is a change in shape that is obvious in the absence of persuasive evidence that this particular configuration is significant. See MPEP 2144.04 IV B Changes in Shape. Further, Gregoire et al. as modified by Dejter, Jr et al. are moot as to the direction of the locking mechanism. However, assuming that such a direction is not already longitudinally displaceable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have such a locking mechanism be longitudinally displaceable as this is a simple rearrangement of parts regarding the positioning/direction of the locking mechanism that would not have modified operation of the device, and the direction of displacement of the locking device is an obvious matter of design choice. See MPEP 2144.04 VI C Rearrangement of Parts.

Regarding claims 67, 68, 99 and 100, Gregoire et al. as modified by Dejter, Jr et al. teach the biopsy devices of claims 66 and 98, including a first housing lid comprising a U-shaped opening at the top thereof, the opening sized to receive a portion of the removable element (Gregoire et al. front end lid/portion Figure 1 receives probe 45 Figure 5), and the second housing lid comprising a first and second U-shaped opening at the top thereof, wherein each of said openings are sized to receive a portion of the removable element (Gregoire et al. back plate 36 and probe 45 Figure 1, also tissue extractor 65, probe slot 39, and detent pin 82, Figures 6 and 7). While Gregoire et al. as modified by Dejter, Jr et al. do not expressly teach the purpose of the slot left of slot 39 in Figure 7, it is clear that its size is at least big enough to receive detent pin 82. Further, such a duplication of U-shaped openings/slots would have been obvious to one having ordinary skill in the art at the time the invention was made as this "duplication of parts has no patentable significance unless a new and unexpected result is produced." (See MPEP 2144.04 VI B Duplication of Parts).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736